IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [47] 1:22-cv-00490-LMM [45] 1:22-cv-01583-LMM [55]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on Defendant's motion to exclude the opinions of David A. Kessler, M.D., from evidence in support of the claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs").[1] Upon due consideration, the Court enters the following Order.

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiffs' claims in other Orders. See Dkt. Nos. [116, 137, 138].

I. BACKGROUND

Paragard is an IUD that is implanted into a patient by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008. Cooper acquired the Paragard NDA from Teva on November 1, 2017.

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected for the removal of her Paragard to be simple and easy. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

Dr. Kessler is a licensed physician, holds a juris doctor degree, and is a former commissioner of the FDA. Plaintiffs retained Dr. Kessler as a regulatory

expert. Dr. Kessler has submitted an expert report in which he opines that the Paragard label did not contain sufficient warnings of breakage at the time Plaintiffs had their Paragards implanted and that Defendant failed to follow standard quality-assurance and manufacturing practices to adequately assess and therefore minimize the risk of Paragard breakage in the body. Dkt. No. [42-10] ¶¶ 19, 20.[2]

Defendant seeks to exclude Dr. Kessler's testimony and opinions under Rule 702 of the Federal Rules of Evidence. It argues that Dr. Kessler's testimony and opinions should be excluded because his methodology is faulty; because he offers opinions that are irrelevant or that he is not qualified to render; and because he offers opinions on issues that have already been resolved or where there is no genuine issue of material fact.

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (cleaned up). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure

the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: whether the theory or technique in question can be (and has been) tested; whether the theory or technique has been subjected to peer review and publication; the known or potential rate of error; and general acceptance of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the

burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotation marks omitted). "Quite the contrary, '[v]igorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (alteration in Quiet Tech.).

III. DISCUSSION

Dr. Kessler has a J.D. from the University of Chicago and is a Harvard-trained licensed physician with extensive experience in pediatrics, regulatory policy, and public health. He served as FDA Commissioner for about seven years and has held senior academic and advisory positions. His expertise

spans regulatory compliance, pharmacovigilance, adverse event reporting, and legal testimony in pharmaceutical and medical device cases. He has published widely in both medical and legal fields and has significant experience in both government and industry settings. Dr. Kessler has previously testified as an expert witness in a broad range of lawsuits, including pharmaceutical and medical device product liability cases.

A. Dr. Kessler's labeling opinions

Dr. Kessler opines that at the time each bellwether plaintiff was implanted with the Paragard, the product label did not adequately warn about the risk associated with breakage of the Paragard T-frame in utero and the likely consequent need for surgery to remove a fragment. Dkt. No. [42-19] ¶¶ 19, 20. He asserts that before any of the plaintiffs had their Paragards placed, Defendant had received reports of breakage of the Paragard T-frame in utero, including information that the T-frame could break with or without embedment of the Paragard in the uterine wall; the T-frame could break upon removal; and breakage could require surgical removal. Id. ¶ 19.c. He contends that Defendant should have responded to the reports by performing a thorough safety assessment of Paragard breakage and updating the label accordingly via the Changes Being Effected ("CBE") process to warn that (1) breakage can occur with embedment, (2) device breakage can occur, (3) breakage can occur upon removal, and (4) breakage can require a surgical removal. Id. ¶¶ 19.d., e., 20, 141.

1. Labeling background and Dr. Kessler's labeling opinions

Defendant argues that Dr. Kessler's opinions on the sufficiency of the warnings on the Paragard label will not be helpful to the finder of fact because the warnings were already adequate. See Dkt. No. [47] at 10-13, 17-20. The Court held on summary judgment, without reliance on Dr. Kessler's expert report, that there is a genuine issue of material fact as to whether the label adequately warned of the risk of breakage. Dkt. No. [149] at 7-11. Thus, the adequacy of the label's warnings and the reasons the label's warnings may not have been adequate are still open questions. Dr. Kessler's testimony therefore will not be limited on this basis.

2. The methodology underpinning Dr. Kessler's proposed labeling changes

Defendant argues that Dr. Kessler's methodology focused on quantifying the frequency of Paragard breakage and therefore does not support his labeling opinions because his labeling suggestions say nothing about frequency and because he did not perform any analysis that would reliably support his opinion that Defendant undercounted breakage events over time. It also contends that the breakage rates are "miniscule." Dkt. No. [47] at 13-17. The Court is not persuaded that Dr. Kessler's labeling opinions should be excluded on these grounds.

Dr. Kessler's analysis was not exclusively focused on frequency. Instead, he analyzed Paragard breakage data to determine whether Defendants could have and should have updated the Paragard label with information that was available

before Plaintiffs had their Paragards placed. See Dkt. No. [42-19] ¶¶ 92, 96, 140, 156. He expressly stated that his "goal was not to ascertain the exact number of breakage reports by year, but instead to determine that the Manufacturers had evidence of breakage reports . . . in the relevant years." Id. ¶ 96. After reviewing the content of Paragard breakage reports beginning in 1989, he found, based on his regulatory and medical education, training, and professional experience, that it was apparent that the risks of breakage and the attendant need for surgery giving rise to the warnings he now advocates were apparent in Defendant's data. See id. ¶¶ 97-113, 141, 143.

The adverse event reports Dr. Kessler analyzed recount incidents where the Paragard broke without embedment, where the Paragard broke after resistance at removal, where surgery was needed to remove parts of a broken Paragard, and, in one report, where the surgical removal of the Paragard also involved removal of the patient's uterus. Id. ¶¶ 97-113. As Plaintiffs point out, the federal regulations require that a drug manufacturer include on the drug label a "Warnings and Precautions" section describing "clinically significant adverse reactions" and an "Adverse Reactions" section describing "undesirable effect[s], reasonably associated with the use of [the] drug[,] . . . for which there is some basis to believe that there is a causal relationship between the drug and the occurrence." 21 C.F.R. § 201.57(c)(6)(i), (7). Defendant's own expert testified that breakage is a clinically significant adverse reaction for Paragard. See Deposition of Jonathan P. Jarow, M.D., at 146. The Court therefore does not have a problem with

Dr. Kessler's concept of adverse event reports influencing whether there should have been an earlier change to the warnings on the Paragard label.

It also bears noting that Defendant, via its Head of Pharmacovigilance, Dr. Siyu Liu, conducted a similar quasi-quantitative review of historical breakage data by which Defendant identified device breakage as a reportable adverse event and submitted the analysis to the FDA to support a label change to add "device breakage" as an adverse reaction. See Dkt. No. [137] at 9-10 (describing how Dr. Liu reached the conclusion after reviewing 90 adverse reports for device breakage).

For these reasons, the Court finds no basis for excluding Dr. Kessler's testimony on grounds that his methodology was wanting.

3. Whether Dr. Kessler is qualified to opine on the adequacy of the label warnings

The Court held in a previous Order that the learned-intermediary doctrine applies in this prescription-drug case. Dkt. No. [138] at 6-8. Under Florida tort law, the question of whether a warning is legally adequate is typically based on the perspective of the "reasonable person."[3] Cates v. Zeltiq Aesthetics, Inc., 73 F.4th 1342, 1350 (11th Cir. 2023) (cleaned up). Where, as here, a medical provider serves as a learned intermediary, the perspective is that of "the reasonable medical provider." Id. (same)

[3] The parties have determined that Florida law applies to the substantive claims of each of the bellwether plaintiffs, except as to Rickard's claim for punitive damages.

Defendant argues that Dr. Kessler is not qualified to offer his opinion that the label did not adequately warn of the risk of Paragard breakage because he is not an OB/GYN, has never counseled a patient on the risks and benefits of Paragard, and has neither inserted nor removed a Paragard. Dkt. No. [47] at 20-21. Plaintiffs, in response, state that they do not intend for Dr. Kessler to testify as a medical expert and that his labeling opinions are based on his expertise as a regulatory expert. Dkt. No. [80] at 32.

Because Plaintiffs are not offering Dr. Kessler as an expert to offer the opinion from the perspective of a medical doctor, this issue is now moot, and Dr. Dr. Kessler may not opine about the warnings Defendant should have given OB/GYNs for the purposes of state tort law.

Defendant does not challenge Dr. Kessler's qualifications to testify as to the sufficiency of the warnings from a regulatory perspective, however. Thus, Dr. Kessler may, as a regulatory expert, offer opinions about whether the warnings were adequate from a regulatory perspective—i.e., whether the FDA would have approved or required a particular warning had certain information been disclosed to it.

4. Dr. Kessler's opinion that Defendant could have used the CBE process to strengthen the breakage warnings

In adjudicating Defendant's motion for summary judgment on preemption grounds, the Court determined that there was newly acquired information that would have allowed Defendant to use the CBE process to add a breakage warning

to the Paragard label.[4] Dkt. No. [137] at 9-13. Whether Defendant could have used the CBE process to strengthen the breakage warnings is therefore no longer at issue in this case. Defendant's motion to exclude testimony on the issue is thus moot.

B. Dr. Kessler's opinions on quality and pharmacovigilance

Dr. Kessler opines that Defendant did not follow standard quality assurance procedures and the FDA's Current Good Manufacturing Practice ("cGMP") regulations to adequately assess and therefore minimize the risk of Paragard breakage in the body. Dkt. No. [42-19] ¶ 21. More particularly, he opines that Defendant failed to "adequately create, monitor, implement or update a robust quality system," "make systemic changes in response to recurring failure modes," and maintain quality and pharmacovigilance systems adequate to assure continued safety of the Paragard product; that Defendant's use of inconsistent and varied coding practices obscured the actual number of events that should have been coded as "device breakages" and thus obscured trends and safety signals related to device breakage; and that Cooper's failure to maintain records of June 2023 audit findings is in violation of cGMP standards. Id.

[4] The Court reached this determination without relying on the opinions of Dr. Kessler. See Dkt. No. [137] at 9-13.

1. Legal import of pharmacovigilance and quality-assurance opinions

Defendant suggests that Dr. Kessler's pharmacovigilance and quality-assurance opinions should be excluded because there is no private right of action to enforce the FDCA; Plaintiffs have withdrawn their manufacturing-defect claims; and the pharmacovigilance and quality-assurance opinions therefore do not fit the facts of the case. Dkt. No. [47] at 24-26. Defendant also argues that Dr. Kessler's opinions regarding pharmacovigilance and quality-assurance issues predating or postdating Defendant's ownership of the Paragard NDA are irrelevant to its liability. Id. at 26. Finally, Defendant contends that the pharmacovigilance and quality-assurance opinions have no legal import because no expert has connected them to the bellwether plaintiffs' claims or injuries. Id.

There is no claim for fraud on the FDA. Dr. Kessler therefore may not imply that incomplete, wrong, or false reports to the FDA or substandard pharmacovigilance and quality-assurance processes form the basis for a claim.

However, the pharmacovigilance opinions and quality-assurance opinions are relevant to Plaintiffs' claims, such as their claims for failure to warn, negligence, design defect, and punitive damages. Defendant has made clear that it plans to introduce argument that the FDA did not order it to change the Paragard. Thus, Plaintiffs may introduce evidence that the FDA did not have the correct adverse-event information and explain why. Aside from the opinion regarding Cooper's alleged failure to maintain records of 2023 audit findings,

which has no apparent relevance to the claims remaining in this case, backward-looking records post-dating Defendant's ownership of the NDA may be relevant to show what Defendant knew or should have known but failed to disclose to the FDA. Since the Paragard design has been essentially the same since its introduction, reports of breakage pre-dating Defendant's ownership of the NDA may be relevant for the same reasons.

In stating the factual basis for those of his opinions where it is relevant that the reports to the FDA were complete and correct, Dr. Kessler can explain that the information provided to the FDA was incomplete or wrong or false. See In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2187, 2018 WL 4212409, at *3 (S.D.W.Va. Sept. 4, 2018) ("[A]n expert may testify as to a review of internal corporate documents . . . for the purpose of explaining the basis for his or her opinions.").

Because Cooper is no longer in the case, Dr. Kessler will not be offering opinions about its alleged failure to maintain records of 2023 audit findings. This issue is now moot. He will otherwise be allowed to testify to the issues Defendant raises.

2. Legal import of Dr. Kessler's "undercounting" opinion

Defendant also challenges the admissibility of Dr. Kessler's opinion that improper coding of device breakage "diluted the actual number of events that were coded as 'device breakages' and obscured trends and safety signals related to device breakage." Dkt. No. [47] at 26-28. It argues that Dr. Kessler does not

and cannot show that "undercounting" actually occurred, and that even if he could, the undercounting theory has no legal import to the case. Id.

The Court finds no merit in these arguments. As discussed above, Dr. Kessler's breakage analysis was conducted to determine whether Defendant could have and should have updated the Paragard warnings with information that was available to it prior to Plaintiffs' use of the Paragard. After reviewing the content of Paragard breakage reports beginning in 1989, Dr. Kessler found, based on his regulatory education, training, and professional experience, that it was apparent that the risks of breakage and the attendant need for surgery were apparent in Defendant's data. See Dkt. No. [42-19] ¶¶ 97-113, 141, 143. Based on his regulatory education, training, and professional experience, he is also qualified to opine on the quality of the coding and the effect substandard coding would have on identification of trends and safety signals.

The Court therefore finds no basis for excluding Dr. Kessler's opinions regarding the quality of the adverse event coding or its effect on identification of trends and safety signals.

3. Dr. Kessler's narrative summaries of company documents and deposition testimony

Defendant argues that Dr. Kessler improperly attempts to serve as a conduit for company documents and deposition testimony under the guise of an expert opinion and that he goes beyond the permissible bounds of expert testimony to speculate on the mental impressions of other people. Dkt. No. [47]

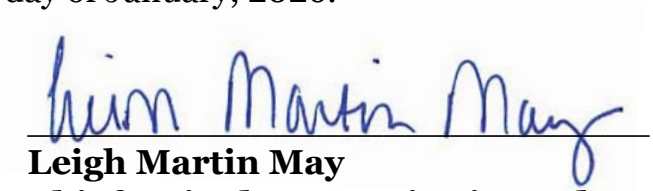
at 28-29. As discussed above, Dr. Kessler can talk about specific documents that support his opinions and that he relied on. See In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2018 WL 4212409 at *3. The Court also notes that Defendant's example of an instance where Dr. Kessler allegedly speculated on the mental impressions of another person is misleading: Dr. Kessler's testimony relied on that person's testimony of her own mental impressions, and Dr. Kessler's testimony therefore is not excludable as speculative. See Deposition of Mariessa Perez-Gibbins at 201-02.

In any event, Dr. Kessler's testimony on company documents and deposition testimony shall be limited to identifying what Defendant knew or should have known and how that knowledge aligns with FDA labeling requirements. If Dr. Kessler's testimony about company documents or deposition testimony goes too far, Defendant can object as to the particular question or recitation.

IV. CONCLUSION

Defendant's motion to exclude the opinions of David A. Kessler, M.D., from evidence in the bellwether cases is **DENIED IN PART**, **AND DENIED AS MOOT IN PART**, as set out above.

IT IS SO ORDERED this 8th day of January, 2026.



Leigh Martin May
Chief United States District Judge